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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,216	12/20/2001	Joel R. Studin	2600.112	3976

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	11

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/022,216	Applicant(s) STUDIN, JOEL R.	
	Examiner Humera N. Sheikh	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-71* is/are pending in the application.

4a) Of the above claim(s) *1-32,36-38,40-43,46-54, 55-59 and 65-69* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-35,39,44,45,60-64,70 and 71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2, 3 & 7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

Receipt of the request for extension of time (1 month) and the Amendment, both filed 07/18/03 is acknowledged.

Claims 40-43 have been *withdrawn* from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Newly elected claims 55-59 and 65-69 have been *withdrawn* from further consideration because they are not directed to or not limited to an analgesic or antihistamine. As such they are considered by the examiner as not being drawn to the elected species of invention, and hence have been withdrawn.

Claims 33-35, 39, 44, 45, 60-64 and 70-71 are pending. Claims 33, 35, 39 and 45 have been amended. New claims 55-71 have been added. Claims 1-32, 36-38, and 46-54 have been cancelled. Claims 40-43, 55-59 and 65-69 have been withdrawn. Claims 33-35, 39, 44, 45, 60-64, 70 and 71 are rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 35, 45 and 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 35, 45 and 64 contain the trademark/trade name *Benadryl*® (diphenhydramine HCL). Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe an *antihistamine* and, accordingly, the identification/description is indefinite.

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 recites the term "*fluid, film-forming carrier*" in line 2, which is indefinite because it is unclear as to how a film-former would be in fluid form. Clarification is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 33, 34, 39, 60-62, 70 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang (US Pat. No. 6,528,086 B2).

Zhang teaches methods and formulations for dermal drug delivery on a human body surface comprising less than solid anesthetic formulations and delivery systems that can be applied to the skin or compromised surfaces and subsequently converted to a soft coherent solid state and then peeled off after the anesthetic effect is achieved, wherein the formulation comprises a topically delivered drug, a conversion agent and a vehicle medium or carrier, wherein the *drug is dispersed in the carrier* and whereby the

formulation contains active ingredients of topical and local *anesthetic* agents and systemic circulation and regional tissue drugs of *analgesics*, hormones and anti-inflammatory agents (see reference column 1, line 1 through col. 14, line 64).

According to Zhang, the topically delivered drug or pharmaceutical can be a single drug, such as a single local anesthetic or a combination of drugs (i.e., eutectic mixture of lidocaine and tetracaine). The drug may be dispersed throughout the formulation in a solid form, dissolved in oil droplets, which are dispersed in the vehicle medium, or in aqueous solution within the vehicle medium. The drug should be capable of transdermal delivery. The vehicle medium facilitates application of the formulation and delivery of the drug. Permeation enhancers may also be added (col. 3, lines 10-58).

The conversion agent provides the formulation with the ability to change from one phase to another more solid and coherent phase, such as from a liquid or cream to a soft solid. The formulation is applied to a patient's skin in such a way as to form a continuous layer of formulation. When the phase change occurs, the solidified formulation is more easily removed from the patient's skin. The formulation does not leave behind residues or films. Zhang teaches that a unique feature of his invention is that the solid phase is coherent and has certain strength so it can be *peeled off* the body surface as a layer, leaving little residual formulation. The formulation will be flexible and not brittle (see col. 3, line 59 – col. 4, line 9).

Zhang teaches the use of polyvinyl alcohol as an ingredient in the cream formulation of his invention (col. 4, lines 22-32).

Various drugs and pharmaceutical agents can be included in the formulation, such as dermatological agents, drugs for promoting wound healing, drugs for treating warts and moles, drugs for treating insect bites and minor cuts, anti-inflammatory agents, analgesics (narcotic agents, steroids), hormones and the like (col. 11, lines 16 – col. 14, line 64).

The various Tables and examples demonstrate different applications of the invention. For example, Table A (Formulation I) at column 7, shows a formulation comprising a pharmaceutical agent (eutectic mixture), polyvinyl alcohol, glycerol, lecithin, Water Lock® and water in various percentage weights wherein it states that Formulation I should be easy to apply and remove (i.e., in form of cream, paste) when applied to the skin, but should form a solid gel so that it can be easily 'peeled off' the skin without leaving a mess on the skin. Tables B and onwards demonstrate anesthetic formulations comprising mixtures of anesthetics and ingredients.

Zhang teaches that one of the advantages of his invention is that it obviates the need to remove the cream from the skin by extensive washing or cleansing of the skin. When the desired anesthetic effect is achieved, the solid gel is peeled off the skin area, leaving virtually no residual mess on the skin. The skin area is anesthetized and if desired can be subjected to a medical treatment or procedure (col. 9, line 45 – col. 10, line 9).

Zhang teaches drug formulations and delivery systems that can be applied to and then peeled off the skin and/or off compromised human body surfaces after the drug delivery is achieved. There is no significant distinction observed between the

instant invention and the prior art since Zhang explicitly teaches methods of drug delivery comprising anesthetic and analgesic agents, whereby the formulation comprises active ingredients, fluid carriers and conversion agents wherein the formulation can be cleanly peeled off the skin.

Claims 35, 44, 45, 63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang (US Pat. No. 6,528,086 B2) as applied to claims 33, 34, 39, 60-62, 70 and 71 above and further in view of Tipton *et al.* (US Pat. No. 5,632,727).

As discussed above, Zhang teaches methods and formulations for dermal drug delivery on a human body surface comprising less than solid anesthetic formulations and delivery systems that can be applied to the skin or compromised surfaces and subsequently converted to a soft coherent solid state and then peeled off after the anesthetic effect is achieved, wherein the formulation comprises a topically delivered drug, a conversion agent and a vehicle medium or carrier, wherein the drug is dispersed in the carrier and whereby the formulation contains active ingredients of topical and local *anesthetic* agents and systemic circulation and regional tissue drugs of *analgesics*, hormones and anti-inflammatory agents (see reference column 1, line 1 through col. 14, line 64).

Zhang teaches the inclusion of active ingredients, such as anesthetics and analgesics dispersed within the carrier and is lacking only in the sense that he does not teach antihistamines in the carrier.

Tipton et al. teach a biodegradable film dressing and methods of using the film dressing to treat injured tissues and deliver biologically active agents wherein the film comprises active agents consisting of antihistamines (diphenhydramine), anesthetics, analgesic agents, anti-inflammatory agents and mixtures and combinations thereof (see reference column 1, line 61 – col. 4, line 29); (col. 9, lines 50-63); claim 19 and abstract.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the formulation of Tipton within the teachings of Zhang because Tipton explicitly teaches combinations and mixtures of various active agents, including antihistamines, anesthetics and analgesics in a film dressing for delivering active agents and treating tissues and similarly Zhang teaches methods and formulations for dermal drug delivery comprising *anesthetic* agents, *analgesics*, anti-inflammatory agents and the like. The expected result would be a highly effective method for administering biologically active agents, as similarly desired by the applicant.

Prior Art made of record, not relied upon and deemed relevant by the Examiner:

US Patent No. 5,446,070 *Mantelle* 08/1995

US Patent No. 4,937,078 *Mezei et al.* 06/1990

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns
October 16, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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